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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,149	11/02/2001	Kristian Dimatteo	498-263	7468

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EXAMINER

HO, UYEN T

ART UNIT PAPER NUMBER

3731

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/003,149

Applicant(s)

DIMATTEO ET AL. *CH*

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Mehta (5,258,042). Mehta disclose a seamless and self-supporting tubular non-textile graft of biocompatible polymeric material having a wall thickness of 75 microns and having opposed open ends to define a fluid passageway therebetween (col. 6, lines 55-68).

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi et al. (6,290,720) in view of Usala (5,922,339). Khosravi et al. disclose a stent-graft comprising a graft (12), a stent (14). Although, Khosravi et al. do not disclose the stent-graft having with biocompatible material, as claimed, attention is directed to the Usala reference which discloses a biocompatible polymeric material as claimed and suggests the polymeric material poly-para-xylylene to be coated on a stent or vascular

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graft in order to prevent material from adhering to the stent or vascular graft and to provide a biocompatible immunoisulatory vehicle suitable for long term implantation of the stent or stent into a body lumen (col. 5, lines 52-64). Usala also suggests a method for coating as claimed (col. 6, line 18 to col. 8, line 24). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to coat the biocompatible polymeric, poly-para-xylylene as claimed onto Khosravi et al.'s stent-graft in order to prevent material from adhering to the stent-graft and to provide a biocompatible surface that will not evoke the immune response for implantation of the stent-graft into a body lumen.

In regarding to the wall thickness of the stent-graft, the range of the wall thickness of the stent-graft as claimed is known in the art. Therefore, it would have been obvious to one having ordinary skill in the art to make the stent-graft of Khosravi having a wall thickness within the range as claimed order to accommodate within a body lumen and provide a necessary support.

Although, Khosravi et al. do not disclose the graft being non-textile, it is known in the art that a non-textile vascular graft being made to minimize the thickness of the graft wall as well as the blood leaking through the wall of the graft. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the graft as disclosed by Khosravi et al. as a non-textile graft in order to minimize the thickness of the graft wall as well as the blood leaking through the wall of the graft. Doing to would optimize the accommodation and support function of the graft in a vessel.

In regarding to the method as claimed, using the method as suggested by Usula would carry out all the steps as claimed.

In regarding to the formula as claimed, since the applicant has not disclosed that having poly-para-xylylene "consists essentially" the formula as claimed to solve any state problem or for any particular purpose it appear that stent would perform equally well with any other formula of the poly-para-xylylene and the frame structure of the formula as claimed are well known.

### ***Response to Arguments***

3. Applicant's arguments filed 6/9/04 have been fully considered but they are not persuasive. The claims do not limit the graft being made from the poly-para-xylylene alone. The poly-para-xylylene can just be a coating on a self-support stent-graft of Khosravi. Applicant argues that then range of the wall thickness of the graft as claimed is not well known. Examiner disagrees. It is well known in the art to make stent or graft or stent-graft having thickness from 10-100 or up to 250 microns (See Buscemi et al. 5,464,450, Mehta 5,258,042). The formula as claimed is a known formula of poly-para-xylylene in the art. In regard to claims 1, 11 as amended, since the applicant has not disclosed that having poly-para-xylylene "consists essentially" the formula as claimed to solve any state problem or for any particular purpose it appear that stent would perform equally well with any other formula of the poly-para-xylylene and the frame structure of the formula as claimed are well known.

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on 703-308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho  
Patent Examiner  
Art Unit 3731

September 9, 2004